

Serial No. 09/849,044

PATENT

REMARKS

In the Office action of May 5, 2003, Paper No. 15, claims 1 and 3-9 are pending and were rejected. Claims 2, 10 and 11 were previously canceled. In particular, claims 1 and 3-7 were rejected under 35 USC 102(e) as being anticipated by Douglas (6,090,128). Claims 8 and 9 were rejected under 35 USC 103(a) as being unpatentable over Douglas in view Babbs (WO 98/25544).

Applicants' attorney thanks Examiner Stewart for the telephone interview of May 4, 2003, in which claim 1 and in particular the Examiner's interpretation of the term "extracellular matrix" was discussed. No agreement was reached.

By this amendment, independent claim 1 is being amended to more fully distinguish over Douglas. In particular, the covering of collagen has an isolated extracellular matrix layer that becomes remodeled by host tissue. First, applicants traverse the Examiner's interpretation of the term "extracellular matrix." The Examiner has taken the ordinary dictionary meaning of "matrix" as -- something within or from which something else originates, develops, or takes form --. The Examiner has interpreted "extracellular" as a promotion of cell tissues. However, the ordinary dictionary meaning of "extracellular" is -- located or occurring outside a cell -- from the American Heritage dictionary. However, the term "extracellular matrix" is a term of art used by one ordinarily skilled in this field. Attached herewith are two similar definitions of "extracellular matrix" from the on-line medical dictionary and the on-line dictionary of cell and molecular biology. As indicated, "extracellular matrix" is -- any material produced by cells and secreted into the surrounding medium --. As further indicated in these definitions, although ecm is produced by cells, it has recently become clear that the ecm can influence the behavior of cells quite markedly, an important factor to consider when growing cells in vitro. As discussed with the Examiner in the telephone interview, applicants' attorney pointed out that the

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covering of collagen having an extracellular matrix that becomes remodeled by host tissue distinguished over Douglas. Various proteins and other growth factors are present in this collagen having an extracellular matrix that promotes the remodeling of tissue coming in contact or proximity therewith. In Douglas, columns 11 and 12, line 65-4, the graft may be comprised of any fabric or plastic materials. There is absolutely no disclosure, teaching or suggestion of the use of a covering of collagen and, more particularly, a collagen having an extracellular matrix that becomes remodeled by a host tissue. By this amendment, applicants have further indicated that the collagen has an isolated extracellular matrix layer that becomes remodeled by host tissue. Support for this extracellular matrix layer is found throughout the specification and depicted in the drawings. More importantly, the understanding of "extracellular matrix" by one ordinarily skilled in the art and indicated by the enclosed definitions would support that this extracellular matrix layer would be produced by cells and secreted into the surrounding medium such as host tissue coming in contact or proximity therewith. The isolated layer adds further support to the claim in that this collagen extracellular matrix layer is harvested or stripped from tissue such as from the small intestine of porcine as indicated in the specification and the many cited references therein. Clearly, a "covering of collagen having an isolated extracellular matrix layer that becomes remodeled by host tissue" is not identically disclosed, taught or even suggested by Douglas, and it is requested that the rejection of independent claim 1, as amended herein, and dependent claims 3-7 under 35 USC 102(e) as being anticipated by Douglas, be withdrawn.

With respect to dependent claims 8 and 9, the particular orientation of the covering is specified in independent claim 1 with the first and second portions being approximately equal and folded back over the proximal end of the stent. Opposite ends of the flat tissue are connected along the seam at the free ends of the covering portions extending equally along the inner and outer surface of the stent. Such configuration is not

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disclosed in Fig. 2 of Babbs or any other portion thereof. This particular configuration recited in claim 1 provides a minimal wall thickness and also minimizes the possibility of blood flowing into and between the covering of collagen, which forms the wall of the stent graft with the stent positioned between the first and second folded back portions. No teaching or suggestion is provided for such configuration in either Douglas or Babbs, and it is requested that the rejection of dependent claims 8 and 9 under 35 USC 103(a) as being unpatentable over Douglas in view of Babbs, be withdrawn.

The reexamination and reconsideration of this application is respectfully requested, and it is further requested that the application be passed to issue.

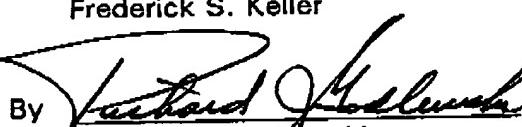
Although the foregoing discussion is believed to be dispositive of the issues in this case, applicants' attorney requests a telephone interview with the Examiner to further discuss any unresolved issues remaining after the Examiner's consideration of this amendment.

Respectfully submitted,

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Date: Aug. 5, 2003

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Enclosures:

Extracellular Matrix from On-line Medical Dictionary
Extracellular Matrix Proteins from On-line Medical Dictionary

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extracellular matrix

Any material produced by cells and secreted into the surrounding medium, but usually applied to the noncellular portion of animal tissues. The ecm of connective tissue is particularly extensive and the properties of the ecm determine the properties of the tissue. In broad terms there are three major components: fibrous elements particularly collagen, elastin or reticulin), link proteins (e.g. Fibronectin, laminin) and space filling molecules (usually glycosaminoglycans). The matrix may be mineralised to resist compression (as in bone) or dominated by tension resisting fibres (as in tendon). The basal lamina of epithelial cells is another commonly encountered ecm. Although ecm is produced by cells, it has recently become clear that the ecm can influence the behaviour of cells quite markedly, an important factor to consider when growing cells in vitro: removing cells from their normal environment can have far reaching effects.

(18 Nov 1997)

Previous: [extracellular enzyme](#), [extracellular fluid](#), [extracellular fluid volume](#)

Next: [extracellular matrix proteins](#), [extracellular space](#), [extracellular toxin](#)

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extracellular matrix proteins

Macromolecular organic compounds that contain carbon, hydrogen, oxygen, nitrogen, and usually, sulfur. These macromolecules (proteins) form an intricate meshwork in which cells are embedded to construct tissues. Variations in the relative types of macromolecules and their organization determine the type of extracellular matrix, each adapted to the functional requirements of the tissue. The two main classes of macromolecules that form the extracellular matrix are: glycosaminoglycans, usually linked to proteins (proteoglycans), and fibrous proteins (e.g., collagen, elastin, fibronectins and laminin).

(12 Dec 1998)

Previous: [extracellular fluid](#), [extracellular fluid volume](#), [extracellular matrix](#)

Next: [extracellular space](#), [extracellular toxin](#), [extracerebral](#)

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